NOV 20 1997

K971329

10. 510(K) SUMMARY

Summary Of Safety And Effectiveness

10.1. General Information

Classification: Class II
Magnetoencephalograph

Common/Usual Name: Magnetoencephalographic (MEG) Device

Proprietary Name: CTF "Whole-Cortex MEG System"

Establishment Registration: to be submitted

Manufacturer:
CTF Systems Inc.
15 - 1750 McLean Ave.
Port Coquitlam, BC
Canada V3C 1M9
Phone: (604) 941-8561
Fax: (604) 941-8565

Performance Standards: no applicable performance standard have been issued under section 514 of the Food, Drug and Cosmetic Act.

10.2. Intended Uses

The CTF "Whole-Cortex MEG System" system is intended for use as a magnetoencephalographic (MEG) device which non-invasively detects and displays biomagnetic signals produced by electrically active nerve tissue in the brain. When interpreted by a trained clinician, the data enhances the diagnostic capability by providing useful information about the location relative to brain anatomy of active nerve tissue responsible for critical brain functions.

10.3. Device Description

The CTF "Whole-Cortex MEG System" integrates up to 200 dc-SQUID axial gradiometers with workstation computers and data acquisition software in order to measure the magnetic signals generated by the intercellular dendritic currents. These detectors positioned in a helmet shaped array which gives the user the ability to record the electrical activity of the entire surface of the brain simultaneously without having to move the position of the probe.

10.4. Safety and Effectiveness

The CTF "Whole-Cortex MEG System" is substantially equivalent to both the Neuromag-122 (K962764) and the Biomagnetic Technologies Magnes Single (K901215A) in safety and effectiveness. The following chart has been compiled to demonstrate that the CTF "Whole-Cortex MEG System" is substantial equivalence to these devices.

Substantial Equivalence Chart:

Parameter	CTF "Whole-Cortex MEG System"	Neuromag-122 (K962764)	Biomagnetic Technologies Magnes Single (K901215A)
No. of SQUID detectors/channels for MEG data:	64 to 200	122	37
Operating Principle	superconducting flux transformer coupled with dc-SQUID controlled by digital flux-locked loop	superconducting flux transformer coupled with dc-SQUID controlled by analog flux-locked loop	superconducting flux transformer coupled with dc-SQUID controlled by analog flux-locked loop
No. of auxiliary channels for other types of data:	88	166	51
Gradiometer:	1 axial first order gradiometer per location	2 orthogonal planar first order gradiometers per location	1 axial first order gradiometer per location
Intersensor spacing:	32 mm (150 sensor configuration)	43-44 mm	20 mm
Gradiometer placement:	64 to 200 locations distributed across the helmet shaped lower tip of a dewar (Optional Caucasian or Oriental head shape).	61 locations distributed across the helmet shaped lower tip of a dewar.	37 locations positioned in a circular array over a concave spherical surface.
Cryogen used:	Liquid Helium	Liquid Helium	Liquid Helium
Coverage:	One acquisition to cover entire head.	One acquisition to cover entire head.	Six to ten acquisitions to cover entire head.
Gantry:	Floor mounted, standard gantry is fixed. Optional gantry tilts to 90°.	Floor mounted, standard gantry tilts up to 30°. Optional gantry tilts to 45°.	Suspended from ceiling, gantry can tilt up to 45°.
Patient Position:	Seated, or lying on back with optional bed.	Seated or supine. Optional chair insert for children	Seated, or lying on back or side.
Head position indicator:	Included	Available	Available
Computer:	HP workstation with UNIX environment	HP workstation with UNIX environment	SUN workstation with UNIX environment
Networking capabilities:	Ethernet connections to other workstations included	Ethernet connections to other workstations available	Ethernet connections to other workstations available

Magnetic shielded room accessories:	Interior DC lights, video camera and monitor and two-way intercom for monitoring patients	Video monitor and two-way intercom for monitoring patients	Interior DC lights, video cameras and two-way intercom for monitoring patients

Intended use comparison:

The **CTF "Whole-Cortex MEG System"** non-invasively measures the magnetoencephalographic (MEG) signals produces by the active tissue of the brain. These signals are displayed and may be interpreted by trained physicians to help localize these active areas. The locations may be correlated to anatomical information of the brain.
Based on the product literature: The **Neuromag-l22** system is intended for use as a magnetoencephalographic (MEG) device which non-invasive detects and displays biomagnetic signals produced by electrically active nerve tissues in the brain, When interpreted by a trained clinician, the data enhances the diagnostic capability by providing useful information about the location relative to brain anatomy of active nerve tissue responsible for critical brain functions.
Based on the product literature: The **Magnes Single** non-invasively detects small biomagnetic signals produced by brain and provides information about the location of electrically active nerve tissue responsible for producing these signals. The data is presented to the physicians in an MEG image, from which they may draw information about the location of critical brain function relative to brain anatomy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

NOV 20 1997

Stephen E. Robinson, Ph.D.
Senior Scientist
CTF Systems, Inc.
15 - 1750 McLean Avenue
Port Coquitlam, British Columbia
CANADA V3C 1M9

Re: K971329
Trade Name: Whole-Cortex MEG System
Regulatory Class: II (two)
Product Code: 84GWQ
Dated: September 5, 1997
Received: September 8, 1997

Dear Dr. Robinson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number (if known): K971329

Device Name: Whole-cortex MEG System (with optional EEG)

Indications For Use:

The CTF Systems Inc. "Whole-Cortex MEG System" non-invasively measures the magnetoencephalographic (MEG) signals (and, optionally, electroencephalographic EEG signals) produced by electrically active tissue of the brain. These signals are recorded by a computerized data acquisition system, displayed, and may then be interpreted by trained physicians to help localize these active areas. The locations may then be correlated with anatomical information of the brain. MEG is routinely used to identify the locations of visual, auditory, somatosensory, and motor cortex in the brain.* MEG is also used to non-invasively locate regions of epileptic activity within the brain. The localization information provided by MEG may be used, in conjunction with other diagnostic data, in neurosurgical planning.

*when routinely used in conjunction with evoked response averaging devices

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971329

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)